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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 9

Complete if Known

Application Number	
Filing Date	June 20, 2003
First Named Inventor	Baskaran Chandrasekar
Group Art Unit	
Examiner Name	

Attorney Docket Number 201267.90011

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

Examiner
Signature

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Substitute for form 1449B/PTO			Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number	
			Filing Date	June 20, 2003
			First Named Inventor	Baskaran Chandrasekar
			Group Art Unit	
			Examiner Name	
Sheet	2	of	9	Attorney Docket Number
201267.90011				

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
AMC		Akishita, M., et al., "Estrogen Inhibits Cuff-induced Intima Thickening of Rat Femoral Artery: Effects on Migration and Proliferation of Vascular Smooth Muscle Cells," <i>Atherosclerosis</i> 130:1-10, 1997.		
AMC		Albuquerque, M.L., et al., "Basic Fibroblast Growth Factor Release by Human Coronary Artery Endothelial Cells is Enhanced by Matrix Proteins, 17-beta Estradiol and a PKC Signaling Pathway," <i>Exp. Cell Res.</i> 245(1):163-169, 1998.		
AMC		Asahara, T., et al., "Local Delivery of Vascular Endothelial Growth Factor Accelerates Reendothelialization and Attenuates Intima Hyperplasia in Balloon-injured Rat Carotid Artery," <i>Circulation</i> 91(11):2793-2801, 1995.		
AMC		Bauriedel, G., et al., "Migratory Activity of Human Smooth Muscle Cells Cultivated from Coronary and Peripheral Primary and Restenotic Lesions Removed by Percutaneous Atherectomy," <i>Circulation</i> 85(2):554-564, 1992.		
AMC		Bonan, R., et al., "Coronary Restenosis: Evaluation of a Restenosis Injury Index in a Swine Model," <i>Am. Heart J.</i> 126(6):1334-1340, 1993.		
AMC		Brewster, M.E., et al., "Use of 2-hydroxypropyl-betacyclodextrin as a Solubilizing and Stabilizing Excipient for Protein Drugs," <i>Pharm. Res.</i> 8(6):792-795, 1991.		
AMC		Chandrasekar, B. and Tanquay, J.F., "Local Delivery of 17-beta Estradiol Decreases Neointima Hyperplasia Following Coronary Following Coronary Angioplasty in Porcine Model," (submitted for publication).		
AMC		Chandrasekar, B., et al., "Coronary Artery Endothelial Protection Following Local Delivery of 17-beta Estradiol During Balloon Angioplasty: A Potential New Pharmacological Approach to Improve Long-term Outcome of Angioplasty," <i>J. Am. Coll. Cardiol.</i> 35(2):58A, 2000.		
AMC		Chen, S.J., et al., "Estrogen Reduces Myointimal Proliferation after Balloon Injury of Rat Carotid Artery," <i>Circulation</i> 93(3):577-584, 1996.		
AMC		Chesebro, J.H., et al., "Restenosis after Arterial Angioplasty: A Hemorrhologic Response to Injury," <i>Am. J. Cardiol.</i> 60:10B-16B, 1987.		
AMC		Clowes, A.W., et al., "Kinetics of Cellular Proliferation after Arterial Injury: Smooth Muscle Cell Growth in the Absence of Endothelium," <i>Lab. Invest.</i> 49(3):327-333, 1983.		

Examiner Signature	<i>Magdalena</i>	Date Considered	<i>9/18/2003</i>
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			Examiner Name	
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OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
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AMC		Collins, P., et al., "Hemoglobin Inhibits Endothelium-dependent Relaxation to Acetylcholine in Human Coronary Arteries In Vivo," Circulation 87(1):80-85, 1993.	
AMC		Cooke, J.P. and Tsao, P.S., "Cytoprotective Effects of Nitric Oxide," Circulation 88(5):2451-2454, 1993.	
AMC		Cornwell, T.L., et al., "Inhibition of Smooth Muscle Cell Growth by Nitric Oxide and Activation of cAMP-dependent Protein Kinase by cGMP," Am. J. Physiol. 267:C1405-C1413, 1994.	
AMC		Currier, J.W. and Faxon, D.P., "Restenosis after Percutaneous Transluminal Coronary Angioplasty: Have We Been Aiming at the Wrong Target?", J. Am. Coll. Cardiol. 25(2):516-520, 1995.	
AMC		Dai-Do, D., et al., "17-Beta Estradiol Inhibits Proliferation and Migration of Human Vascular Smooth Muscle Cells: Similar Effects in Cells from Postmenopausal Females and in Males," Cardiovas. Res. 32:980-985, 1996.	
AMC		Dangas, G., and Fuster, V., "Management of Restenosis after Coronary Intervention," Am. Heart J. 132(2):428-436, 1996.	
AMC		Doenicke, A., et al., "A Comparison of Two Formulations for Etomidate, 2-hydroxypropyl-beta-cyclodextrin (HPCD) and Propylene Glycol," Anesth. Analg. 79:933-939, 1994.	
AMC		Fischell, T.A., et al., "Coronary Artery Vasoconstriction Routinely occurs after Percutaneous Transluminal Coronary Angioplasty: A Quantitative Arteriographic Analysis," Circulation 78(6):1323-1334, 1988.	
AMC		Foegh, M.L., et al., "Estradiol Inhibition of Arterial Neointima Hyperplasia after Balloon Injury," J. Vasc. Surg. 19(4):722-726, 1994.	
AMC		Frijlink, H.W., et al., "The Pharmacokinetics of Beta-cyclodextrin and 2-hydroxypropyl-beta-cyclodextrin in the Rat," Pharm. Res. 7(12):1248-1252, 1990.	
AMC		Furchtgott, R.F. and Zawadski, J.V., "The Obligatory Role of Endothelial Cells in the Relaxation of Arterial Smooth Muscle by Acetylcholine," Nature 288:373-376, 1980.	

Examiner Signature	<i>Alvin L. Lott</i>	Date Considered	<i>9/8/2003</i>
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Sheet

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First Named Inventor	Baskaran Chandrasekar
Group Art Unit	
Examiner Name	

Attorney Docket Number

201267.90011

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

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AMC	✓	Geary, R.L., et al., "Conjugated Equine Estrogens Inhibit Progression of Atherosclerosis but have no Effect on Intimal Hyperplasia or Arterial Remodeling Induced by Balloon Catheter Injury in Monkeys," J. Am. Coll. Cardiol. 31(5):1158-1164, 1998.	
AMC	✓	Gilligan, D.M., et al., "Effects of Physiological Levels of Estrogen on Coronary Vasomotor Function in Postmenopausal Women," Circulation 89(6):2545-2551, 1994.	
AMC	✓	Hayashi, Y., et al., "Functional and Anatomical Recovery of Endothelium after Denudation of Coronary Artery," Am. Physiol. Soc. H1081-H1090, 1988.	
AMC	✓	Hayashi, T., et al., "Estrogen Increases Endothelial Nitric Oxide by a Receptor-mediated System," Biochem. Biophys. Res. Commun. 214(3):847-855, 1995.	
AMC	✓	Hishikawa, K., et al., "Up-regulation of Nitric Oxide Synthase by Estradiol in Human Aortic Endothelial Cells," FEBS Let. 360:291-293, 1995.	
AMC	✓	Hoon, T.J., et al., "Bioequivalence of a 17-beta Estradiol Hydroxypropyl-beta-cyclodextrin Complex in Postmenopausal Women," J. Clin. Pharmacol. 33:1116-1121, 1993.	
AMC	✓	Hyder, S.M., et al., "Uterine Expression of Vascular Endothelial Growth Factor is Increased by Estradiol and Tamoxifen," Cancer Res. 56(17):3954-3960, 1996.	
AMC	✓	Iafrati, M.D., et al., "Estrogen Inhibits the Vascular Injury Response in Estrogen Receptor alpha-deficient Mice," Nat. Med. 3(5):545-548, 1997.	
AMC	✓	Karas, R.H., et al., "Human Vascular Smooth Muscle Cells Contain Functional Estrogen Receptor," Circulation 89(5):1943-1950, 1994.	
AMC	✓	Karas, S.P., et al., "Coronary Intimal Proliferation after Balloon Injury and Stenting in Swine: An Animal Model of Restenosis," J. Am. Coll. Cardiol. 20(2):467-474, 1992.	
AMC	✓	Kauffman, R.F., et al., "Comparative Effects of Local vs. Systemic Administration of Estrogen upon Vascular Responses to Balloon Injury," Circulation 92(8):1628, 1995.	

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Alexand Tutton

Date Considered

9/18/2003

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STATEMENT BY APPLICANT

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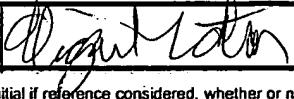
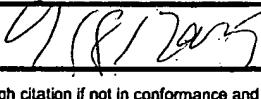
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of 9

Complete if Known

Application Number	
Filing Date	June 20, 2003
First Named Inventor	Baskaran Chandrasekar
Group Art Unit	
Examiner Name	
Attorney Docket Number	201267.90011

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
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AMC		Kawana, H., et al., "Gender Differences in Improvement of Endothelium-dependent Vasodilation after Estrogen Supplementation," J. Am. Coll. Cardio. 30(4):914-919, 1997.
AMC		Keany, J.F., et al., "17-Beta-estradiol Preserves Endothelial Vasodilator Function and Limits Low-density Lipoprotein Oxidation in Hypercholesterolemic Swine," Circulation 89(5):2251-2259, 1994.
AMC		Kim-Schulze, S., et al., "Expression of An Estrogen Receptor by Human Coronary Artery and Umbilical Vein Endothelia Cells," Circulation 94(6):1402-1407, 1996.
AMC		Kim-Schulze, S., et al., "Estrogen Stimulates Delayed Mitogen-Activated Protein Kinase Activity in Human Endothelial Cells via an Autocrine Loop that Involves Basic Fibroblast Growth Factor," Circulation 98:413-421, 1998.
AMC		King, S.B., III, et al., "Endovascular Beta-radiation to Reduce Restenosis after Coronary Balloon Angioplasty: Results of the Beta Energy Restenosis Trial (BERT)," Circulation 97:2025-2030, 1998.
AMC		Kolodgie, F.D., et al., "Estradiol Attenuates Directed Migration of Vascular Smooth Muscle Cells In Vitro," Am. J. Pathol. 148(3):969-976, 1996.
AMC		Kraskinski, K., et al., "Estradiol Accelerates Functional Endothelial Recovery after Arterial Injury," Circulation 95(7):1768-1772, 1997.
AMC		Kristensson, J.K., et al., "Dexamethasone-cyclodextrin-polymer Co-complexes in Aqueous Eye Drops: Aqueous Humor Pharmacokinetics in Humans," Invest. Ophthalmol. Vis. Sci. 37(6):1199-1203, 1996.
AMC		Kublick, H., et al., "Nasal Absorption of 17-beta-estradiol from Different Cyclodextrin Inclusion Formulations in Sheep," Eur. J. Pharma. Biopharm. 42(6):320-324, 1996.
AMC		Kuiper, G.G.J.M., et al., "Cloning of a Novel Estrogen Receptor Expressed in Rat Prostate and Ovary," Proc. Natl. Acad. Sci. USA 93:5925-5930, 1996.
AMC		Kullo, I.J., et al., "Enhanced Endothelium-dependent Relaxations after Gene Transfer of Recombinant Endothelial Nitric Oxide Synthase to Rabbit Carotid Arteries," Hypertension 30(3):314-320, 1997.

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Sheet	6	of	9	Attorney Docket Number	201267.90011

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
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AMC	✓	Levine, R.L., et al., "Medroxyprogesterone Attenuates Estrogen-mediated Inhibition of Neointima Formation after Balloon Injury of the Rat Carotid Artery," Circulation 94(9):2221-2227, 1996.			
AMC	✓	Lindner, V., et al., "Regrowth of Arterial Endothelium: Denudation with Minimal Trauma Leads to Complete Endothelial Cell Growth," Lab. Invest. 61(5):556-563, 1989.			
AMC	✓	Lindner, V., et al., "Basic Fibroblast Growth Factor Stimulates Endothelial Regrowth and Proliferation in Denuded Arteries," J. Clin. Invest. 85:2004-2008, 1990.			
AMC	✓	Lindner, V., et al., "Increased Expression of Estrogen Receptor- α mRNA in Male Blood Vessels after Vascular Injury," Circ. Res. 83:224-229, 1998.			
AMC	✓	Losordo, D.W., et al., "Variable Expression of the Estrogen Receptor in Normal and Atherosclerotic Coronary Arteries of Premenopausal Women," Circulation 89(4):1501-1510, 1994.			
AMC	✓	Ludmer, P.L., et al., "Paradoxical Vasoconstriction Induced by Acetylcholine in Atherosclerotic Coronary Arteries," N. Eng. J. Med. 315(17):1046-1051, 1986.			
AMC	✓	MacRitchie, A.N., et al., "Estrogen Upregulates Endothelial Nitric Oxide Synthase Gene Expression in Fetal Pulmonary Artery Endothelium," Circ. Res. 81(3):355-362, 1997.			
AMC	✓	Malekianpour, M., et al., "Abnormal Coronary Vasomotion and Angina after Successful Coronary Angioplasty," Circulation 94(8):1-560, 1996 (Abstract).			
AMC	✓	Mancini, G.B.J., et al., "Automated Quantitative Coronary Arteriography: Morphologic and Functional Validation In Vivo of a Rapid Digital Angiographic Method," Circulation 75(2):452-460, 1987.			
AMC	✓	McLaren, J., et al., "Vascular Endothelial Growth Factor is Produced by Peritoneal Fluid Macrophages in Endometriosis and Is Regulated by Ovarian Steroids," J. Clin. Invest. 98(2):482-489, 1996.			
AMC	✓	Mendelsohn, M.E. and Karas, R.H., "Estrogen and the Blood Vessel Wall," Curr. Opin. Cardiol. 9:619-626, 1994.			

Examiner Signature	<i>Wingard Collier</i>	Date Considered	<i>9/18/2008</i>
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AMC	✓	Mikkola, T., et al., "Effect of Physiological Concentrations of Estradiol on PGI-2 and NO in Endothelial Cells," 25(2):141-147, 1996.			
AMC	✓	Morales, D.E., et al., "Estrogen Promotes Angiogenic Activity in Human Umbilical Vein Endothelial Cells In Vitro and in a Murine Model," <i>Circulation</i> 91(3):755-763, 1995.			
AMC	✓	Mori, T., et al., "Short Term Estrogen Treatment Prior to and Following Balloon Injury of Rat Carotid Artery Effectively Blunts the Vascular Injury Response," <i>J. Am. Coll. Cardiol.</i> 33(2 Supp. 1): 267A, 1999 (Abstract).			
AMC	✓	Mosselman, S., et al., "ERB: Identification and Characterization of a Novel Human Estrogen Receptor," <i>FEBS Let.</i> 392:49-53, 1996.			
AMC	✓	Moura, A., et al., "Intramural Delivery of Agent via a Novel Drug-delivery Sleeve: Histological and Functional Evaluation," <i>Circulation</i> 92(8):2299-2305, 1995.			
AMC	✓	O'Brien, J.E., et al., "Relation Between Estrogen Replacement Therapy and Restenosis after Percutaneous Coronary Interventions," <i>J. Am. Coll. Cardiol.</i> 28(5):1111-1118, 1996.			
AMC	✓	O'Keefe, J.H., et al., "Estrogen Replacement Therapy after Coronary Angioplasty in Women," <i>J. Am. Coll. Cardiol.</i> 29(1):1-5, 1997.			
AMC	✓	Oparil, S., et al., "Sexually Dimorphic Response of the Balloon-injured Rat Carotid Artery to Hormone Treatment," <i>Circulation</i> 95(5):1301-1307, 1997.			
AMC	✓	Perrot-Appelat, M., "Questradiol and Proliferation of Vascular Cells," 54(3):333-337, 1999.			
AMC	✓	Post, M.J., et al., "The Relative Importance of Arterial Remodeling Compared with Intimal Hyperplasia in Lumen Renarrowing after Balloon-Angioplasty," <i>Circulation</i> 89(6):2816-2821, 1994.			

Examiner Signature	<i>Allegretto</i>	Date Considered	<i>6/18/2003</i>
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AMC	✓	Reis, S.E., et al., "Ethinyl Estradiol Acutely Attenuates Abnormal Coronary Vasomotor Responses to Acetylcholine in Postmenopausal Women," <i>Circulation</i> 89(1):52-60, 1994.	T ²
AMC	✓	Roselli, M., et al., "Circulating Nitric Oxide (Nitrite?Nitrate) Levels in Postmenopausal Women Substituted with 17-beta-estradiol and Norethisterone Acetate: A Two-year Follow-up Study," <i>Hypertension</i> 25(2):848-853, 1995.	
AMC	✓	Sarkar, R., et al., "Nitric Oxide Reversibly Inhibits the Migration of Cultured Vascular Smooth Muscle Cells," <i>Cir. Res.</i> 78(2):225-230, 1996.	
AMC	✓	Selzman, C.H., et al., "Estrogen Replacement Inhibits Intimal Hyperplasia and the Accumulation and Effects of Transforming Growth Factor Beta1," <i>J. Surg. Res.</i> 80(2):380-385, 1998.	
AMC	✓	Seo, K.K., et al., "Involvement of Endothelial Nitric Oxide Synthase in the Impaired Endothelium-dependent Relaxation of Cavernous Smooth Muscle in Hypercholesterolemic Rabbit," <i>J. Androl.</i> 20(2):298-306, 1999.	
AMC	✓	Shimokawa, H., et al., "Porcine Coronary Arteries with Regenerated Endothelium have a Reduced Endothelium-dependent Responsiveness to Aggregating Platelets and Serotonin," <i>Cir. Res.</i> 61(2):256-270, 1987.	
AMC	✓	Speir, E., et al., "Estrogen Inhibits Transcription Factor and Cell Adhesion Molecule Activation in Cytokine-stimulated Human Coronary Smooth Muscle Cell via Antioxidant Effects," <i>Circulation Suppl. I</i> :1-220, 1998 (Abstract).	
AMC	✓	Spyridopoulos, I., et al., "Estrogen-receptor-mediated Inhibition of Human Endothelial Cell Apoptosis: Estradiol as a Survival Factor," <i>Circulation</i> 95(6):1505-1514, 1997.	
AMC	✓	Sullivan, T.R., Jr., et al., "Estrogen Inhibits the Response-to-injury in a Mouse Carotid Artery Model," <i>J. Clin. Invest.</i> 96:2482-2488, 1995.	
AMC	✓	Tanaka, H., et al., "Sustained Activation of Vascular Cells and Leukocytes in the Rabbit Aorta after Balloon Injury," <i>Circulation</i> 88(4):1788-1803, 1993	
AMC	✓	Tanaka, H., et al., "Proliferating Arterial Smooth Muscle Cells after Balloon Injury Express TNF-alpha but not Interleukin-1 or Basic Fibroblast Growth Factor," <i>Arterioscler. Thromb. Vasc. Biol.</i> 16(1):12-18, 1996.	

Examiner Signature	<i>Allyed V. Johnson</i>	Date Considered	<i>6/20/2003</i>
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				Filing Date	June 20, 2003
				First Named Inventor	Baskaran Chandrasekar
				Group Art Unit	
				Examiner Name	
Sheet	9	of	9	Attorney Docket Number	201267.90011

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AMC	✓	Varenne, O., et al., "Local Adenovirus-mediated Transfer to Human Endothelial Nitric Oxide Synthase Reduces Liminal Narrowing After Coronary Angioplasty in Pigs," Circulation 98:916-926, 1998.				
AMC	✓	Venkov, C.D., et al., "Identification of Authentic Estrogen Receptor in Cultured Endothelial Cells: A Potential Mechanism for Steroid Hormone Regulation of Endothelial Function," Circulation 94(4):727-733, 1996.				
AMC	✓	Weiner, C.P., et al., "Induction of Calcium-dependent Nitric Oxide Synthases by Sex Hormones," Proc. Natl. Acad. Sci. USA 91:5212-5216, 1994.				
AMC	✓	Wellman, G.C., et al., "Gender Differences in Coronary Artery Diameter Involve Estrogen, Nitric Oxide, and Ca ²⁺ -dependent K ⁺ Channels," Circ. Res. 79(5):1024-1030, 1996.				
AMC	✓	Williams, J.K., et al., "Short-term Administration of Estrogen and Vascular Responses of Atherosclerotic Coronary Arteries," J. Am. Coll. Cardio. 20(2):452-457, 1992.				
AMC	✓	Yoon Young-Sup, et al., "Local Intraluminal Infusion of Oestradiol Containing Liposome in Rat Carotid Balloon Injury Model," Eur. Heart J. 19:616, 1998.				
AMC	✓	Zhang, Y.-Q., et al., "Effects of Gender and Estradiol Treatment on Focal Brain Ischemia," Brain Res. 784(1/2):321-324, 1998.				

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